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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,820	01/28/2002	Jonathan S. Bogan	0399.2025-002	2441
21005	7590	04/24/2006	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			RIGGINS, PATRICK S	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,820	BOGAN ET AL.	
	Examiner	Art Unit	
	Patrick S. Riggins	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 32-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 25-31 and 54-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt is acknowledged of an amendment filed 12/23/05. Claims 1, 6, 15, 25, and 55-57 were amended. Presently claims 1-57 are pending with claims 22-24 and 32-53 withdrawn from consideration as being drawn to non-elected inventions. Claims 1-21, 25-31, and 54-57 are presently under examination.

Oath/Declaration

2. The Declaration filed 12/23/05, executed by Inventor Bogan is acknowledged and accepted.

Response to Amendment

3. The rejections under 35 U.S.C 112, second paragraph are withdrawn due to Applicant's amendment to the claims.

4. Applicant's arguments, see the bottom of page 14 through the top of page 16 of the amendment, filed 12/23/05, with respect to the rejection under the judicially created doctrine of obviousness-type double patenting have been fully considered and are persuasive. The rejection of claims 1, 10, 11, 15, 20, 21, 25, 30, 31, 54, and 57 has been withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. Claims 12-21 and 25-31, readable on enriched expression libraries and methods utilizing enriched expression libraries, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new rejection.

7. The claims as written could reasonably be construed as being directed to a genus of enriched expression libraries which comprise any nucleic acid encoding a protein capable of altering GLUT4 trafficking in the presence of insulin stimulation, and methods to further enrich these libraries. The description as filed only provides sufficient written support for nucleic acids encoding specifically disclosed UBX-domain-containing proteins. The claims embrace those nucleic acids encoding proteins yet to be identified or characterized. Further claims 15 and 25, at steps f) and c), respectively, comprise steps of using the enriched library, which has not been defined structurally.

8. With respect to a required description of a representative number of species of nucleic acids present in a library enriched by the method of the invention, it is clear that at the time of the invention the mechanisms of insulin-stimulated GLUT4 trafficking in cells was not particularly well characterized. It would seem that this is indeed the purpose of applicants' invention. It is apparent that on the basis of applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or assays and/or any other unspecified structure containing unspecified sequences that are only described by functional

language, wherein the detailed and common structure of the genera of the claimed therapeutic polynucleotides was not described; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structure(s) of component(s) that are linked in order to exhibit the disclosed biological functions as contemplated by the as-filed specification.

9. It is not sufficient to support the present claimed invention directed to enriched expression libraries with no common structure being claimed in the presently pending claims because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any and/or all other material(s) of agents other than those known in the prior art, as admitted by the as-filed specification, having the biological functions as contemplated by the specification and the claims. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified molecular structures of enriched expression libraries, with no instruction regarding the structural contents of that enriched library, which must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. V. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person

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skilled in the art would recognize that the inventors had possession of the claimed invention.

(*Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998)).

Claims 1-21, 25-31, and 54-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying cells comprising DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane from cells comprising an expression library comprising DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane comprising:

- a) maintaining cells which comprise an expression library comprising DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane under conditions in which the protein is expressed;
- b) stimulating the cells with insulin;
- c) sorting the cells of b) which comprise an altered proportion of GLUT4 at the cell surface upon stimulation with insulin due to the presence of DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane, relative to the proportion of GLUT4 at the surface of cells stimulated with insulin in the absence of DNA encoding a protein involved in insulin stimulated GLUT 4 trafficking at the plasma membrane;
- d) expanding the sorted cells from step c);
- e) resorting the cells expanded in step d); and
- f) expanding the cells sorted in step e);

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thereby identifying cells from step f) comprising DNA encoding a protein involved in GLUT4 trafficking at the plasma membrane;

does not reasonably provide enablement for a method of enriching an expression library where cells comprising the library are stimulated with insulin and sorting cells comprising an altered proportion of GLUT4 at the cell surface or the expression library enriched by the method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This is a new rejection.

10. When considering whether the specification in view of the prior art enables the skilled artisan to practice the claimed invention without undue levels of experimentation a number of factors are considered in making this determination as delineated by *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

11. The claims as drawn embrace a method of enriching an expression library where the expression library plays no role in the sorting or isolation of the DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane. There is no teaching in the prior art how one could identify a DNA encoding a protein involved in insulin stimulated GLUT4 trafficking at the plasma membrane based upon the claimed breadth. In short, there is no teaching as to what role the expression library would play in the methods as claimed. Stimulation

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of the cells with insulin would necessarily lead to an increase in the proportion of GLUT4 on the cell surface. Thus as presently drawn the method would not lead to enrichment of an expression library since the method would simply lead to isolation of cells effectively stimulated by insulin. There is no limitation present in the claims as presently drawn, specifying that the sorted cells are those insulin stimulated cells comprising a DNA encoding a protein involved in insulin stimulated GLUT4 trafficking which have an altered proportion of GLUT4 on the cell surface relative to those insulin stimulated cells that do not comprise a DNA encoding a protein involved in insulin stimulated GLUT4 trafficking. As such, the claimed methods fail to teach the skilled artisan how to enrich the expression library, as the method as drawn fails to lead to expression library enrichment.

Conclusion

12. No claim is allowed.

13. As there are new grounds of rejection not necessitated by amendment, this Office Action is NOT final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102.

The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, consisting of a stylized 'D' followed by a long, sweeping horizontal line that ends in a small upward flick.

Patrick Riggins, Ph.D.
Examiner
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DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER